DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 1, 2014

Omron Healthcare, Inc.
% Mr. Paul Dryden
Consultant
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K142917
Trade/Device Name: Omron BP652N (HEM-6300-Z) with APS
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 2, 2014
Received: October 7, 2014

Dear Mr. Paul Dryden,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): __K142917_____

Device Name: __ Omron BP652N (HEM-6300-Z) with APS____

Indications For Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environments of Use: Home
Patient Population: Adult

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR **Over-The-Counter Use** __X__
(Per 21 CFR 801.109)

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Omron Healthcare, Inc.
1925 West Field Court Tel - 847-247-5626
Lake Forest, IL 60045 USA Fax- 847-680-5626

Official Contact: Renee Thornborough – Director QA/RA

Proprietary or Trade Name: Model BP652N(HEM-6300-Z) with APS

Common/Usual Name: Noninvasive blood pressure measurement system.

Classification Name/Code: DXN – Noninvasive blood pressure measurement system.

21CFR 870.1130
Class II

Device: Model BP652N(HEM-6300-Z) with APS

Predicate Device: Model BP652N (HEM-6300-Z) K123498
Braun Series BP 200 Series K003732

Device Description:
This device originally received clearance under 510(k) K123498.

The device is an automatic non-invasive blood pressure system. The device is battery powered by 2 "AAA" batteries, there is no connection to external power. The device inflates a wrist cuff with an integral pump, then deflates the cuff via an electronically controllable valve. During inflation the cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic pressure.

The device has a memory function that automatically stores up to 100 of the latest measurements. It can also display an average of the last three values

The device also detects the appearance of irregular heartbeats during measurement.

As originally submitted under 510(k) K123498, the device contained the APS feature. The feature was removed prior to clearance.

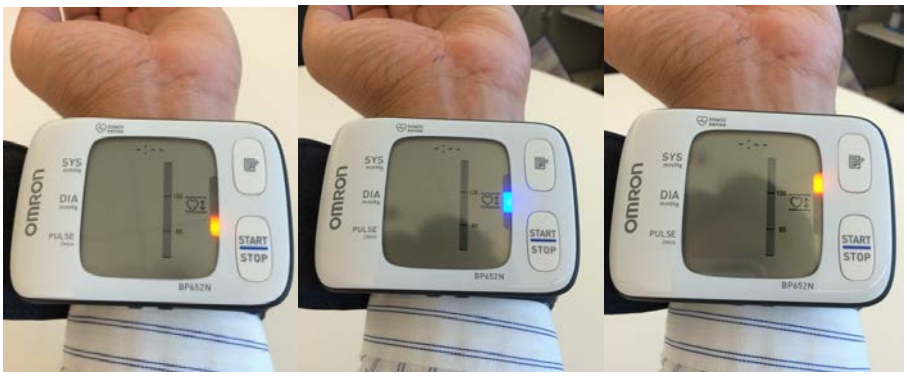
This submission is for the addition of the Advanced Positioning Sensor (APS) into the device. The APS is an aid to help the user determine if the cuff is at the correct height in relationship to the heart. The addition of APS does not change the intended use of the device. The addition of APS does not alter the fundamental scientific technology. There are no changes in hardware. There are no changes in the software algorithm which

determines blood pressure or pulse rate. The addition of the APS feature is an optional feature which the user can elect to use. The APS feature does not alter the accuracy of the device, but serve to assist the user in positioning the device at the level of the heart. Though there is no change in algorithm a clinical study in accordance with ANSI/AAMI/ISO 81060-2:2013 was performed to validate the clinical accuracy of the device when the arm is positioned by use of the APS, see **Section 20**.

Description of APS:

The Advanced Positioning Sensor is an aid to help the user determine if the cuff is at the correct height in relation to the heart. It makes this determination based on the reading of an accelerometer (to measure the angle of the arm in relation to the table) integral to the device.

The APS has no interface to the software algorithm which determines blood pressure or pulse rate, it is a visual feedback to the user indicating whether the device is positioned appropriately in accordance with the APS angle measurement criteria as below.



Too Low **Correct** **Too High**

As above, there are no changes to the hardware, blood pressure or pulse rate algorithms.

Intended User
Home user

Patient Population
This device is intended for use on adults.

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Indications for Use:

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environment of Use:

Home

Contraindications

There are no known contraindications.

Predicate Device Comparison

The BP652N(HEM-6300-Z) with APS was compared to the predicates Model BP652N (HEM-6300-Z) K123498 and Braun Series BP 200 Series K003732 as in the device comparison table below.

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Device Comparison

	PREDICATE **Omron BP652N (HEM-6300-Z)** **K123498**	**PREDICATE** **Braun BP2000 series K003732**	**Device Under Review** **Omron BP652N (HEM-6300-Z) with APS**	**Comment**
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The Braun PrecisionSensor™ (BP2000 series) wrist blood pressure monitor is indicated for use for the noninvasive measurement of blood pressure (systolic and diastolic} and pulse rate in adults, in a home use setting. Use may be initiated by the individual or as part of a hypertension monitoring and management program supervised by a health care provider.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Identical K123498
Patient Population	Adult	Adult	Adult	Identical K123498 and K003732
Environment of Use	Home	Home	Home	Identical K123498 and K003732
Prescriptive	OTC	OTC	OTC	Identical K123498 and K003732
Patient Connection	Yes via cuff	Yes via cuff	Yes via cuff	Identical K123498 and K003732
Technology	Oscillometric	Oscillometric	Oscillometric	Identical K123498 and K003732
Advanced Positioning Sensor	-	Device has position Sensor	Added*	Identical in function to K003732 Braun BP2000 series
Measurement range	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Pressure: 0-300 mmHg Pulse rate: 40 to 160 bpm	Pressure: 0-299 mmHg Pulse rate: 40 to 180 bpm	Identical K123498
Accuracy of pressure indicator	+/- 3 mmHg or 2% of reading	+/- 3 mmHg	+/- 3 mmHg or 2% of reading	Identical K123498
Pressure sensor	Piezo resistance sensor	Not specified	Piezo resistance sensor	Identical K123498
Accuracy Pulse Rate	+/-5%	+/-5%	+/-5%	Identical K123498 and K003732
Inflation Method	Piezo-electric pump	Not specified	Piezo-electric pump	Identical K123498
Deflation Method	Internal valve	Electronic control valve	Internal valve	Identical K123498 and K003732
Display Type	LCD	LCD	LCD	Identical K123498 and K003732
Irregular pulse detection	Yes	No	Yes	Identical K123498

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Power Source	AAA batteries	AAA batteries	AAA batteries	Identical K123498 and K003732
Operating Conditions	Temperature: 10° to 40 ° C Humidity: 15 to 85% RH	Temperature: 10° to 40 ° C Humidity: <85%	Temperature: 10° to 40 ° C Humidity: 15 to 85% RH	Identical K123498
Storage Conditions	Temperature: -20 ° to 60 ° C Humidity: 10 to 95% RH	Temperature: -20 ° to 60 ° C Humidity: <85%	Temperature: -20 ° to 60 ° C Humidity: 10 to 95% RH	Identical K123498
Dimensions	89(W) x 61(D) x 13(H) mm	Not sepcified	89(W) x 61(D) x 13(H) mm	Identical K123498
Weight	80g	Not sepcified	80g	Identical K123498

- **By "added" we mean that the feature was re-enabled thus restoring it to the state it was in when originally submitted under 510(k) K123498**

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Differences Between Other Legally Marketed Predicate Devices
The Omron BP652N (HEM-6300-Z) with APS is viewed as substantially equivalent to the predicate devices because: The BP652N (HEM-6300-Z) with APS uses the exact same technology and has identical indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
The indications for use are identical.

Prescriptive – The BP652N (HEM-6300-Z) with APS and predicates are OTC.

Design and Technology – The BP652N (HEM-6300-Z) with APS has equivalent design and technology when compared to the predicates.

Performance and Specifications – The BP652N (HEM-6300-Z) with APS has equivalent specifications of performance compared to the predicates.

Compliance with standards – The BP652N (HEM-6300-Z) with APS and predicate device (Omron BP652N (HEM-6300-Z) K123498) declare compliance with the identical standards: SP10, IEC 60601-1 and IEC 60601-1-2.

Materials –
The patient contacting materials of the cuffs has been tested in accordance with ISO 10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Intracutaneous Reactivity and are identical to Omron BP652N (HEM-6300-Z) K123498 . **Section 15** contains a Materials Certification attesting to this.

Patient Population –
The BP652N (HEM-6300-Z) with APS and predicates are indicated for adults

Non-Clinical Testing Summary:

We have performed bench tests and found that the BP652N (HEM-6300-Z) with APS met all requirements specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to IEC 60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance to AAMI SP10

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Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2: 2013 is documented in **Section 20.**

Substantial Equivalence Conclusion

Omron maintains that the BP652N (HEM-6300-Z) with APS is substantially equivalent to the predicate devices Model BP652N (HEM-6300-Z) K123498 and Braun Series BP 200 Series K003732 in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards